K121229

510(k) SUMMARY

JUL 2 3 2012

SUBMITTER:	Sorin Group Italia S.r.l. 86, Via Statale 12 Nord 41037 Mirandola (MO) Italy
CONTACT PERSON:	Luigi Vecchi Phone: 011 39 0535 29811 Fax: 011 39 0535 25229
DATE PREPARED:	April 24, 2012
DEVICE TRADE NAME:	INSPIRE 8 DUAL hollow fiber oxygenator with integrated hardshell venous/cardiotomy reservoir
COMMON NAMES:	Hollow Fiber Oxygenator with integrated hardshell venous/cardiotomy reservoir Hollow Fiber Oxygenator Hardshell Venous/Cardiotomy Reservoir
CLASSIFICATION NAMES:	Cardiopulmonary Bypass Oxygenator/ Cardiopulmonary Bypass Heat Exchanger/ Cardiopulmonary Bypass Blood Reservoir/ Cardiopulmonary Bypass Defoamer/
PREDICATE DEVICE:	D903 AVANT 2 Ph.I.S.I.O. Adult Hollow Fiber Oxygenator with Ph.I.S.I.O. coating (K033323)

DEVICE DESCRIPTION:

The INSPIRE 8 DUAL is consisting of an oxygenator, integrated with a heat exchanger (INSPIRE 8M), and a hardshell venous/cardiotomy reservoir (INSPIRE HVR DUAL). The reservoir is connected to the gas exchange module by means of a molded fitting joint.

The INSPIRE 8 DUAL is a high efficiency microporous hollow fiber membrane oxygenator, integrated with a heat exchanger, connected to a hardshell venous/cardiotomy reservoir.

The device can be operated at flow rates up to 8 liters per minute (l/min).

The hollow fiber membrane oxygenator provides oxygenation and carbon dioxide removal from venous or suctioned blood. The integrated heat exchanger controls blood temperature and allows the use of hypothermia or aids in the maintenance of

normothermia during surgery. The integrated hardshell reservoir collects, defoams, filters venous and suction blood, and can be used post-operatively for chest drainage.
The INSPIRE 8 DUAL is a modified version of the currently marketed integrated oxygenator/hardshell venous cardiotomy reservoir system D903 AVANT 2 Ph.I.S.I.O (hereinafter referred to as D903 AVANT).

INDICATION FOR USE:
The intended use for the two elements that constitute the integrated device are:

INSPIRE 8M: Hollow Fiber Oxygenator
The INSPIRE 8M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8M is intended to be used for 6 hours or less.

INSPIRE HVR DUAL: Hardshell Venous/Cardiotomy Reservoir
The INSPIRE HVR DUAL is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR DUAL can be used post-operatively for chest drainage. INSPIRE HVR DUAL is intended to be used for 6 hours or less.

TECHNOLOGICAL CHARACTERISTICS:
The INSPIRE 8 DUAL has the same fundamental technological characteristics, principles of operation and control mechanisms as the predicate device.
Sorin believes that the INSPIRE 8 DUAL is substantially equivalent to the D903 AVANT on the basis of operating principles and basic function.
The INSPIRE 8 DUAL and the D903 AVANT share the same fundamental technological characteristics except for some modifications that do not affect the basic device function. Any differences do not raise any new issues of safety and effectiveness.

The INSPIRE 8 DUAL is ethylene oxide sterilized and has a non-pyrogenic fluid path. It is for single use only.

NON CLINICAL TEST RESULTS:
Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of materials.

IN VITRO TEST RESULTS:
In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Oxygenators 510(k) Submissions; Final Guidance for Industry and FDA Staff" issued on November 13, 2000, "Guidance for Extracorporeal Blood Circuit Defoamer 510(k) Submissions; Final Guidance for Industry and FDA" issued on November 29, 2000 ISO 7199 "Cardiovascular implants and artificial organs - Blood-gas exchangers (oxygenators)"; ISO 15675 "Cardiovascular implants and artificial organs — Cardiopulmonary bypass systems — Arterial blood line

filters" and ISO 15674, "Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags".
In vitro testing was carried out to demonstrate both the substantial equivalence with the predicate device and also to comply with safety and effectiveness requirements.
Testing supplied in the 510(k) premarket notification includes performance tests and physical/mechanical integrity tests that demonstrate compliance with performance specifications.
The tests that were performed are listed in the following summary table. The INSPIRE 8 DUAL passed each test mentioned in the table below.

TEST	TEST CLASSIFICATION	TEST TITLE
1	Physical/Mechanical	Oxygenating module structural integrity
2	Physical/Mechanical	Reservoir structural integrity
3	Physical/Mechanical	Oxygenating module blood, water, gas pathway integrity
4	Physical/Mechanical	Reservoir blood pathway integrity
5	Functional/Performance	Oxygenating module blood volume capacity
6	Functional/Performance	Reservoir blood rest volume
7	Functional/Performance	Oxygenating module gas transfer performance/blood side pressure drop
8	Functional/Performance	Oxygenating module heat exchange performance/water side pressure drop
9	Functional/Performance	Reservoir air handling
10	Functional/Performance	Reservoir break-through time and volume
11	Functional/Performance	Reservoir defoaming efficiency
12	Functional/Performance	Reservoir dynamic priming volume / Hold-up
13	Functional/Performance	Reservoir filtration efficiency - venous section
14	Functional/Performance	Reservoir filtration eficiency - cardiotomy section
15	Functional/Performance	Reservoir flow rate capacity
16	Functional/Performance	Reservoir pressure drop
17	Functional/Performance	Integrated device hemolysis
18	Functional/Performance	Integrated device blood compatibility
19	Functional/Performance	Oxygenating module leaching of coating
20	Functional/Performance	Reservoir leaching of coating

TEST	TEST CLASSIFICATION	TEST TITLE
21	Functional/Performance	Integrated device flaking of coating
22	Functional/Performance	Oxygenating module uniformity of coating
23	Functional/Performance	Reservoir uniformity of coating

CONCLUSIONS:

The results of *in vitro* studies demonstrate that the INSPIRE 8 DUAL performs in a manner substantially equivalent to the D903 AVANT predicate device with respect to the relevant functional parameters. Test results of this study demonstrate the INSPIRE 8 DUAL is equivalent to the predicate device with respect to device function.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 23 2012

Sorin Group Italia s.r.l.
c/o Mr. Barry Sall
Principal Consultant
Parexel International Consulting
195 West Street
Waltham, WA 02451

Re: K121229
Trade/Device Name: Inspire 8 DUAL Hollow Fiber Oxygenator with Integrated Hardshell Venous/Cardiotomy Reservoir
Regulation Number: 21 CFR 870.4350
Regulation Name: Cardiopulmonary Bypass Oxygenator
Regulatory Class: Class II
Product Code: DTZ
Dated: April 24, 2012
Received: April 24, 2012

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use:

INSPIRE 8M: Hollow Fiber Oxygenator

The INSPIRE 8M is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It provides gas exchange support and blood temperature control. INSPIRE 8M is intended to be used for 6 hours or less.

INSPIRE HVR DUAL: Hardshell Venous/Cardiotomy Reservoir

The INSPIRE HVR DUAL is intended for use in adult and small adult surgical procedures requiring cardiopulmonary bypass. It collects, defoams and filters venous blood and suction blood. INSPIRE HVR DUAL can be used post-operatively for chest drainage. INSPIRE HVR DUAL is intended to be used for 6 hours or less.

Prescription Use __X__		Over-the-Counter Use_____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K12 229